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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,408	03/12/2001	Mathew F. Ogle	1416.20US01	1108

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

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DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/804408

Applicant(s)

Cyle et al

Examiner

K. A. H.

Group Art Unit

1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 2/10/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-28 + 34-43 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-28 + 34-43 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

The amendment of 2/10/03 amended claims 34 and 36, and added claims 38-43.

Claims examined on the merits are 1-28 and 34-43 which are all claims in the application.

5 Applicants state that a Supplemental IDS and Form 1449 was filed August 19, 2002, and have supplied a copy of the 1449 and of a return postcard from the Patent and Trademark office showing a filing date of 8/19/02. However, the application does not contain the Supplement IDS, and the IDS did not reach the application file. The documents listed on  
10 form 1449 of the IDS should be resupplied.

***Claim Rejections - 35 USC § 103***

~~Claims 1-28 and 34-43 are rejected under 35 U.S.C. 103(a) as being~~  
unpatentable over Ogle et al (5,958,669) in view of Yang et al (5,935,168) for reasons in the previous office action of 10/2/02 and for  
15 reasons herein.

The claims are drawn to tissue containing linkers bonded to tissue and bridge molecules bonded between two or more of the linkers, and to a method of crosslinking tissue to prepare the tissue having linkers and bridge molecules, or to tissue containing modified sites having bridge  
20 molecules bonded to two or more of the modified sites, and to a method of crosslinking tissue to prepare the tissue having modified sites and bridge molecules.

Ogle et al disclose crosslinking tissue to fix tissue by reacting the tissue with glutaraldehyde.

Yang et al disclose crosslinking tissue with glutaraldehyde, and then reacting with a diamine followed by reacting with additional glutaraldehyde (col 1, line 43 and claims 8-10).

After reacting with glutaraldehyde as disclosed by Ogle et al, it  
5 would have been obvious to react with a diamine and then with additional glutaraldehyde as suggested by Yang et al. Bridges as required by the present claims will inherently result.

#### ***Response to Arguments***

Applicant's arguments filed 2/10/03 have been fully considered but  
10 they are not persuasive.

Applicants urge that in Ogle et al and Yang et al, the tissue is crosslinked with glutaraldehyde, and there is no coupling of one end of glutaraldehyde to a bridge molecule. However, all glutaraldehyde will not contain both ends bound to tissue when crosslinking occurs in Ogle et  
15 al and Yang et al, and when the diamine is added there will be some free ends of the glutaraldehyde that will react with an amine of the diamines. In an embodiment of the present invention, the present specification discloses (page 24, lines 21-22) that the linker and bridge molecule can be applied to the tissue sequentially. If both ends of glutaraldehyde  
20 react with tissue as asserted by applicants, then this embodiment will not work since the tissue is contacted with the glutaraldehyde in the absence of the bridge molecule as in Ogle et al and Yang et al. The fact that this sequential embodiment works supports that some free aldehyde groups will remain after crosslinking tissue with glutaraldehyde as  
25 disclosed by Ogle et al and Yang et al. Furthermore, Yang et al in a

final step reacts the tissue with glutaraldehyde after reacting with a diamine. This will result in the diamine being the linker and the glutaraldehyde being the bridge molecule which will have one end coupled to an amine of a diamine bound to tissue and the other end coupled to an amine of another diamine bound to tissue. The conditions of dependent claims would have been obvious matters of choice in view of the disclosures of the references, and no result is seen from the conditions of these claims that would have been unexpected from that obtained when performing the invention of the independent claims.

10       **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

~~A shortened statutory period for reply to this final action is set~~  
to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of  
15 this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the  
20 statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on

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Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

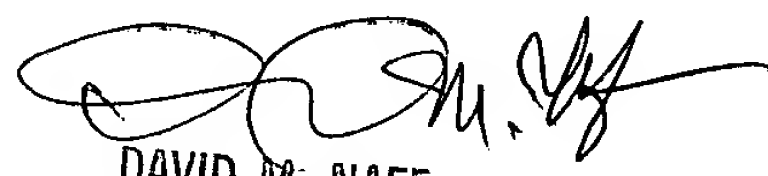
If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

10 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1651

DMN  
5/19/03